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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

ZEMAN, ROBERT A

ART UNIT

PAPER NUMBER

1645

NOTIFICATION DATE

DELIVERY MODE

06/16/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocketing@medimmune.com

DETAILED ACTION

The amendment and response filed on 4-3-2009 are acknowledged. Claims 1-2, 4, 8-9, 19-26 and 43-51 have been canceled. Claims 52-65 have been added. Claims 52-65 are pending and currently under examination.

Claim Rejections Withdrawn

The rejection of claims 1-2, 4, 8-9, 19-26 and 43-51 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn. Cancellation of said claims has rendered the rejection moot.

The rejection of claims 1-2, 4, 8-9, 19-26 and 43-51 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn. Cancellation of said claims has rendered the rejection moot.

New Grounds of Rejection

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 52-65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended the claim to recite "...as numbered according to the EU index as in Kabat, ..." This phrase does not appear in the specification, or original claims as filed. While the specification discloses that the exemplary sequences utilize the Kabat numbering system, the specification makes no mention of the EU index. Therefore this limitation is new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 53-54 and 58-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Said claims recite differing amino acid for the same residue of the baseline IgG1 molecule (position 239). Claims 53 and 54 recite that the baseline sequence has a cysteine at position 239 while claims 58 and 59 recite that said position is a threonine. It is unclear how two different amino acids can occupy the same position in a baseline sequence. Consequently, the skilled artisan would not be able to determine the metes and bounds of the claimed invention.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT A. ZEMAN whose telephone number is (571)272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1645

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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/Robert A. Zeman/
Primary Examiner, Art Unit 1645
June 10, 2009